Food and Drug Administration, HHS

529 1030 Formalin solution

529.1044 Gentamicin sulfate in certain other dosage forms.

529.1044a Gentamicin sulfate intrauterine solution.

529.1044b Gentamicin sulfate solution.

529.1115 Halothane.

529.1186 Isoflurane.

529.1526 Nifurpirinol capsules.

529.2090 Salicylic acid.

529.2150 Sevoflurane.

529.2464 Ticarcillin powder.

529.2503 Tricaine methanesulfonate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§529.50 Amikacin sulfate intrauterine solution.

- (a) Specifications. Each milliliter of sterile aqueous solution contains 250 milligrams of amikacin (as the sulfate).
- (b) Sponsor. See No. 000856 and 059130 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. Two grams (8 milliliters) diluted with 200 milliliters of sterile physiological saline per day for 3 consecutive days.
- (2) Indications for use. For treating genital tract infections (endometritis, metritis, and pyometra) in mares when caused by susceptible organisms including *E. coli, Pseudomonas* spp., and Klebsiella spp.
- (3) Limitations. For intrauterine infusion in the horse only. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 9640, Mar. 8, 1983, as amended at 53 FR 27852, July 25, 1988; 62 FR 15110, Mar. 31, 1997; 62 FR 23358, Apr. 30, 1997]

§ 529.360 Cephalothin discs.

- (a) Specifications. Cephalothin discs have a uniform potency of micrograms cephalothin per disc.
- Sponsor. See No. $\S510.600(c)$ of this chapter.
- (c) Conditions of use. (1) The discs are used for determining the in vitro susceptibility of bacteria to cephaloridine and cephalonium.
- (2) For veterinary laboratory diagnosis only.

[40 FR 13881, Mar. 27, 1975, as amended at 64 FR 404, Jan. 5, 1999]

§ 529.400 Chlorhexidine tablets and suspension.

- (a) Specification. Each tablet and each 28-milliliter syringe of suspension conof chlorhexidine tain 1 gram dihydrochloride.1
- (b) Sponsor. See No. 000856 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet disolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.1

(2) Indications for use. For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine

dihvdrochloride.1

(3) Limitations. Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external genitalia. Use a clean, sterile inseminating pipette for administrating solutions and suspensions. Treatment may be repeated in 48 to 72 hours.1

[43 FR 10705, Feb. 23, 1979]

§529.469 Competitive exclusion culture.

- (a) Specifications. Each packet of lyophilized culture contains either 2,000 or 5,000 doses in frozen pellets to be reconstituted for use.
- (1) For 2,000-dose packet, add contents of one 2,000-dose packet of reconstitution powder to 490 milliliters of deionized water. Mix. Add contents of one 2,000-dose packet of lyophilized culture. Mix thoroughly.
- (2) For 5,000-dose packet, add contents of one 5,000-dose packet of reconstitution powder to 1,250 milliliters of deionized water. Mix. Add contents of one 5,000-dose packet of lyophilized culture. Mix thoroughly. Allow to stand for 45 minutes before use. Use within 5 hours of reconstitution.
- (b) Sponsor. See No. 032761 in §510.600(c) of this chapter.
 - (c) [Reserved]

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information